Study Protocol

Long-term work outcomes and the efficacy of multidisciplinary rehabilitation programs on labor force participation in cancer patients - a protocol for a longitudinal prospective cohort study

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Abstract

Background. Many cancer survivors experience late effects of cancer treatment and therefore struggle to return to work. Norway provides rehabilitation programs to increase labor force participation for cancer survivors after treatment. However, the extent to which such programs affect labor force participation has not been appropriately assessed. This study aims to investigate i) labor force participation, sick leave and disability rates among cancer survivors up to 10 years after being diagnosed with cancer and identify comorbidities contributing to long-term sick leave or disability pensioning; ii) how type of cancer, treatment modalities, employment sectors and financial- and sociodemographic factors may influence labor force participation; iii) how participation in rehabilitation programs among cancer survivor affect the long-term labor force participation, the number of rehospitalizations and incidence of comorbidities.

Design and methods. Information from four medical, welfare and occupational registries in Norway will be linked to information from 163,279 cancer cases (15.68 years old) registered in the Norwegian Cancer Registry from 2004 to 2016. The registries provide detailed information on disease characteristics, comorbidities, medical and surgical treatments, occupation, national insurance benefits and demographics over a 10-year period following a diagnosis of cancer.

Expected impact of the study for Public Health. The study will provide important information on how treatment, rehabilitation and sociodemographic factors influence labor force participation among cancer survivors. Greater understanding of work-related risk factors and the influence of rehabilitation on work-participation may encourage informed decisions among cancer patients, healthcare and work professionals and service planners.

Introduction

Cancer, late effects and ability to work

Europe has 3.2 million new cases of cancer each year, and 1 of 4 people will be diagnosed with cancer.[1,2] Currently, more than 260,000 people who have or have had cancer live in Norway. About 160,000 of these have survived 5 years or more after the cancer diagnosis and can be described as long-term cancer sur-

Significance for public health

This study could potentially determine the influence of cancer treatment, rehabilitation and sociodemographic factors on labour force participation and use of social benefits and health care resources. Data from five nationwide medical, welfare and occupational registries from the whole cancer population in Norway over a ten-year period following diagnosis will be analyzed. In addition, the study will expand the knowledge on risk factors for rehospitalization, sick leave and disability, and provide important health-related, financial and sociodemographic information of patients referred to rehabilitation. The study has the potential to provide solid evidence to guide treatment options and develop social benefit programs for a large and vulnerable patient population.

vivors.[3] Cancer survivors are at risk of developing late effects that can persist throughout life.[4]

Almost half of cancer survivors are of working age (15-65 years old).[5] The prevalence of cancer survivors of working age is expected to grow in industrialized countries because of ageing populations, increasing retirement age and continuing improvements in cancer treatment.[1] Many cancer survivors experience persisting side effects of treatment and struggle to return to work, and are at risk of permanently leaving the labor force. Cognitive limitations, coping issues, fatigue, depression and anxiety are reported to influence ability to return to work.[6] In addition, physical problems, such as difficulties with lifting and treatment-induced menopausal symptoms, are frequently described to affect functioning at work.[6] Cancer survivors with fatigue are also more likely to experience reduced ability to work compared with age-matched controls.[7] A recently published systematic review showed that impaired physical functioning negatively affectedreturn-to-work and the ability to work among breast cancer survivors.[8]

Labor force participation after cancer

In general, work is good for people's health, and especially for mental health and quality of life.[9] In addition, work is important to secures income and good living conditions for the workers and their families. Many cancer survivors have difficulties in returning to work. Studies from both the United States and Europe have shond that average return to work rates are ranging from 39% to 77% among all cancer survivors of working age.[10] In addition, cancer survivors are 1.37 times more likely not to be employed than healthy controls.[5] Although studies indicate that the return to work rate among cancer survivors has increased during recent years, the success rate differs with the cancer site and treatment burden, with early-stage breast cancer and cancer of the female reproductive organs showing a better chance than lung cancer and gastrointestinal cancer.[11] Unfortunately, research on long-term labor force participation (>5 years) among cancer survivors is scarce. Most studies have only investigated the return to work and not the extent to which cancer survivors return to a sustainable and lasting work situation. Based on clinical experience, many people with cancer are eager to return to work, but experience that they have to make adjustments at work, are not able to work full time or have to change work or occupation. It has been suggested that cancer survivors who return to work may not be able to stay in work for a long period or that they over time have to make great changes in work and/or occupation to achieve a sustainable work situation.[12]

Studies from Norway show that cancer survivors experience reduced ability to carry out tasks and engage in paid work and reduced energy to change to another job.[13,14] Torp and associates showed that the employment rate of women who survived cancer declined over 5 years compared with a healthy control group, but this did not apply to men who survived cancer.[16] Nevertheless, the sick leave rates of cancer survivors were constantly higher for both male and female workers compared with the control group 5 years after diagnosis.[16] In another study in Norway, 26% of cancer survivors had to make adjustments in the workplace, and the most common adjustment was reducing the number of working hours per week.[13] As a consequence, many cancer survivors face financial strain because of decreased labor force participation.[17] The cancer survivors receiving work allowance benefits after 1 year of sick leave seem to especially report sustained reduced income.[18] Most of the studies on work-related issues among people with cancer in Norway are rather dated.[14-16,19] They therefore do not cover the late effects of the most recent cancer treatments. In addition, no studies have investigated labor force participation issues among Norwegian cancer survivors at all ages (15-68 years) in a long-term perspective (>5 years).

Factors affecting the labor force participation of cancer survivors

Cancer is a heterogeneous disease with wide variation in treatment modalities and late effects associated with the various diagnoses and related treatments. Studies confirm that certain disease-specific factors affect the ability to work to a greater extent than others, but the conclusions are far from clear and precise. Especially cancer survivors who have had chemotherapy often change employment status or main occupation.[10,20] Hauglann and associates showed that people with breast cancer have a significantly increased risk of receiving disability pension compared with a cancer-free control group.[21] Lung cancer, leukemia and cancer of the nervous system stand out as diagnoses that are associated with an especially poor employment rate.[1,15]A meta-analysis shows that labor force participation can present challenges for groups with breast and head or neck cancer.[5] In addition to diagnosis, tumor stage, cancer treatment and comorbidity decrease the probability that cancer survivors return to work and maintain the ability to work, especially for those who work in low-skilled and/or physically demanding jobs.[22]

The studies on predictors of labor force participation among cancer survivors in Norway confirm the results in the international studies showing negative effects of some diagnoses and of being exposed to chemotherapy.[16,23] However, one study using registry data from Norway from 2000 to 2004 showed that socioeconomic factors were more important for increased sick leave rates than diagnosis, stage and treatment modalities.[16] Nevertheless, this may have changed in recent years because of changes in treatment modalities and more severe or new types of late effects.

Work-related interventions to promote labor force participation

A multidisciplinary approach is often used to support cancer patients return to work process, work retention, work performance and work satisfaction. This approach may include psychological, physical, vocational, job placement services and vocational rehabilitation, occupational (such as educating employers and implementing work adjustments) or legislative (such as antidiscrimination acts) interventions.[1]

The individual need for rehabilitation after cancer vary with diagnosis according to the type of treatment, the severity of late effects, sociodemographic factors, personality and vulnerability. Multidimensional specialized rehabilitation programs are designed to promote the coping and self-management abilities of people with cancer.[24] Both physical and psychosocial interventions are combined in the same program to cover the various dimensions of cancer rehabilitation. Importantly, several of the factors that are associated with difficulty in labor force participation can be modified,[24], and specialized multidisciplinary cancer rehabilitation represents a measure that can promote labor force participation among cancer survivors.[1]

Norway has several rehabilitation programs within the specialist health care system for people with cancer, including both out-

patient and inpatient rehabilitation programs. Information about who is referred to and use these rehabilitation services after a cancer diagnosis is very scare. Knowledge is lacking about the potential of these interventions to promote labor force participation. A small study from Norway showed that respectively 73% and 76% of patients with breast and gynecological cancer returned to work 6 months after discharge from inpatient and outpatient rehabilitation.[24] However, the study did not include a control group of patients who had not participated in rehabilitation and does not allow to estimate treatment effect. In conclusion, there is insufficient evidence to conclude that rehabilitation after cancer has the potential to promote labor force participation in Norway.

The impact of a rehabilitation on return to work and work participation in a long-term perspective among cancer survivors urgently needs to be investigated. We will therefore conduct a longitudinal prospective registry-based study called CANWORK (Cancer and Work) to provide information on labor force participation, long-term sick leave and disability trajectories, risk factors for not participating in the labor force and the efficiency of cancer rehabilitation programs to promote labor force participation among people with cancer.

Aims and hypotheses

This CANWORK study has four main aims: i) to investigate labor force participation, sick leave and disability rates among cancer survivors up to 10 years after being diagnosed with cancer; ii) to identify comorbidities contributing to long-term sick leave or disability pensioning; iii) to investigate how the type of cancer, treatment modalities, employment sectors and financial and sociodemographic factors may influence labor force participation after cancer diagnosis; iv) to assess how participating in rehabilitation affects the long-term labor force participation, the number of rehospitalizations and incidence of comorbidities of cancer survivors.

We hypothesize that i) The labor force participation will decrease over a 10 year period, while sick leave and disability rates increase during the same period. ii) The key barriers to labor force participation will include regional or metastatic cancer at diagnosis, comorbidities, age, adjuvant therapy, education, living with an employed partner and low income. iii) The participation in multidisciplinary rehabilitation programs will increase labor force participation and reduce sick leave and disability rates.

Methodology

Study design

This is a prospective longitudinal cohort study based on health and social data from public registries in Norway.

Study population

The study population comprises people with cancer of working age (15-68 years) at the time of diagnosis (n=163,279) of both sexes and with all cancer diagnoses from 2004 to 2016. When applicable, the project will extract matched controls from data including the remaining Norwegian population (about 3.5 million subjects).

Data collection

The study will use the Norwegian Cancer Registry for enrolment, and additional data will be retrieved through record linkage with three mandatory national registries: the Norwegian Patient Registry, Norwegian Prescription Database and Statistics Norway/Norwegian Labor and Welfare Administration.

The study will use data on employment contracts including start and stop dates, contractual work hours and data on changes in contractual work hours according to Statistics Norway's (the national statistical institute of Norway) categorization. Employment data from 1 year before diagnosis will be included. Labor-force participation, number of rehospitalizations and prevalence of comorbidities are specific outcomes for the evaluation of rehabilitation. Labor-force participation will be defined as being employed during the 90 days prior to cancer diagnosis and at measurement in a given time period (year, month) thereafter. In addition, working hours will be analyzed to investigate the influence of rehabilitation on the amount of work particiapation beside having a work contract. Working hours per week will be monitored among the employed each year, divided into three categories: (a) 30 hours or more (full-time); (b) 20-29.9 hours (long part-time):

Table 1. Source and type of data collected in the project.

Source of data	Type of data
Norwegian Patient Registry	Diagnoses for all diseases (ICD-10), treatment procedures for all diseases (NOMESCO Classification of Medical Procedures, Norwegian Classification of Surgical Procedures, Anatomical Therapeutic Chemical Classification System, cytostatic codes), treatment institution, rehabilitation institution, referring unit, rehabilitation scheme, treatment and death. Specifically for rehabilitation outcome: Incidence of comporbidities will be retrived based on number of diagnoses registered on each patients. Number of re-hospitalizations after rehabilitation will be retrieved from Norwegian Patient Registry.
Statistics Norway/Norwegian Labor and Welfare Administration registry	Employment status (having a work contract, working hours per week), sociodemographic and economic status, income for patient and household, cost of social benefit program, early retirement and loss of productivity and primary diagnosis (ICD-10) for social benefits.
Norwegian Cancer Registry	Diagnosis, specific tumor information, specific tumor therapy, previous cancer treatment and comorbidities
Norwegian Prescription Database	Drug use: drug name and active ingredient, quantity, strength, timing and costs

ICD-10, International Statistical Classification of Diseases and Related Health Problems, version 10.

(c) less than 20 hours (short part-time). A normal working week in Norway is 37.5 hours per week. Number of re-hospitalizations after rehabilitation will be retrieved and counted from the Norwegian Patient Registry. This will include a combination of information regarding acute care, inpatient rehabilitation and long-term hospital stays. The prevalence of comorbidities will be calculated by information provided in the Norwegian Patient Registry and Norwegian Prescription Database. Individual comorbidities will be recorded and converted to comorbidity categories according to the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10).

Sources and types of data

The registry sources and types of data are outlined in Table 1 and described further below. The project will use an authorized and established data-linking infrastructure between the registries, and the project group will receive a data file in which each person with cancer is represented by a unique personal project serial number. Thus, all data will be anonymized.

Disease- and treatment-specific variables

The disease- and treatment-specific variables will include diagnosis (ICD-10 classification), date of diagnosis, number of treatments, treatment status; type of treatment (surgery, chemotherapy, radiation, hormone therapy), date of recurrence of cancer or new cancer diagnosis, number of admissions to hospital, duration of rehabilitation, type of rehabilitation program, drug use, previous cancer treatment, comorbidities, cause and time of death and information regarding geographical health care utilization. Cancer diagnoses will be classified using the second topographic level of categorization according to the International Classification of Diseases for Oncology, third edition.[25]

Demographic and socioeconomic data

The demographic and socioeconomic data will include sex, age, number of children, children's ages, cohabitation status, education status, finances, income, employment sector, type of work and other detailed variables.

In official statistics from Statistics Norway, a reference week in November is used to categorize individuals as employed, self-employed or unemployed. Our data will include this. To capture all employment, we will use data on employment contracts, including start and stop dates as well as contractual work hours and data on changes in contractual work hours.

Using data from Statistics Norway/Norwegian Labor and Welfare Administration we will identify sickness spells among employees and transitions into partial or full disability.

Statistical analysis

Alternative statistical approaches

We want to make causal inferences in investigating the aims of the project. Traditionally, randomized controlled trials have been viewed as the gold standard for exploring the effects of an intervention. Given our research aims and data, a randomized controlled trial is not feasible. However, numerous statistical techniques have evolved to the point at which observational data are used and recommended to perform natural or quasi-natural experiments. In addition, in some settings, natural experiments may be preferred over randomized controlled trials since they can generate causal evidence with high external validity.[26] The main challenge of natural experiments is to ensure that the researcher has not manipulated exposure. Thus, there is a possible, or even likely, problem of selection bias. In natural experiments, it is possible to control for both observed and unobserved confounding, which may substantially reduce selection bias. Observed confounding can be adjusted for through various matching techniques.[27] To adjust for unobservable confounding, a few techniques have been recommended for epidemiology and health systems research: instrumental variables; regression discontinuity; interrupted time series; difference-in-differences and fixed-effects designs.[28] Fixed-effects designs are deemed useful when using registry data including many respondents with regular and detailed collection over time[29], as in the registry data used in this project.

Challenges with a natural experiment

With available data covering a long time span we aim to use some of the techniques mentioned above that would enable us to reduce the bias caused by unobserved heterogeneity. When carrying out a natural experiment or a quasi-natural experiment in which two comparable groups have been subjected to two different schemes during the period of study (such as cancer versus no cancer or rehabilitation versus no rehabilitation), the issue of endogeneity of cancer survivors' enrollment in rehabilitation programs must be correctly addressed. This is straightforwardly controlled for in randomized controlled trials in which cancer survivors are randomly assigned to a program. However, it has to be more explicitly taken into account and controlled when the selection for a program cannot be assumed to be independent of the observable or unobservable employability characteristics of cancer survivors. In this latter case, the selection bias (either self-selection by cancer survivors themselves, selection of cancer survivors by employers and health care professionals or a combination of these) could dramatically distort the estimated parameters. Moreover, in order not to lose information provided by people who have been diagnosed with cancer between 2004 and 2016 as controls (or non-treated) and not cases (or treated) until the date of the cancer diagnosis, dynamic treatment models will be considered.[30]

Difference-in-difference and fixed-effects regression

Difference-in-differences and fixed-effects regression can be applied with a wide variety of regression models, and we will use appropriate techniques to analyze the research questions in the project. The most viable approach to answer research questions related to sick leave rate, disability rate, prediction of sick leave and disability and characteristics of the rehabilitation population is to apply either a logit model with fixed effects or a linear probability model with fixed effects to estimate the changes in rates over time. We will do both to substantiate our results. In addition, we will also consider using duration models (such as Cox regression) with fixed effects. When fixed effects are used, it is not possible to estimate the effect of time-invariant characteristics. Thus, we will analyze separate subgroups (such as by sex or by cancer diagnosis) to describe pertinent differences between groups.

Fixed-effects analysis adjusts for all time-invariant characteristics, and thus there is a reduced need for matching cases and controls (when applicable). However, as a mean to further increase comparability between cases and controls, we will apply matching techniques (such as by means of propensity scores or direct matching), possibly with time-varying characteristics. All analysis will be two-sided, the level of significance will be set at $p<0.05$, and analysis will mainly be performed using the statistics package STATA.

Discussion and expected results of the study

The CANWORK study will evaluate long-term labor force participation among cancer survivors and the impact of multidisciplinary rehabilitation programs on labor force participation in a long-term perspective. Because of inadequate scientific evidence, the recommendations for providing social support and cancer rehabilitation interventions are mostly based on short-term studies with subpopulations of cancer survivors and often solely on the clinical experience and interests of doctors and other health care personnel.[24,31] The CANWORK study has the potential to provide solid evidence regarding the impact of multidisciplinary rehabilitation on labor force participation, and the results can be important for development of future clinical pathways for cancer survivors. The results from the study may also expand the knowledge on the incidence of comorbidities and how they influence cancer survivors' labor force participation and the risk factors for rehospitalization, sick leave and disability. In addition, the study will also provide information on the health-related, financial and sociodemographic characteristics of the people referred to rehabilitation.

A methodological challenge for registry-based research in most countries is that linking data from nationwide registries with health-related and socioeconomic variables is prohibited. However, in the Nordic countries, linking data between registries based on a personal identification number is legal and practically possible. The Nordic registry infrastructure therefore represents an important advantage for longitudinal research in health, welfare and working life for designing public policies. The epidemiological approach to be used in this project has contributed to major scientific discoveries between risk factors and cancer and is considered a very solid method, since it enables analysis with integration of factors from several social and health-related fields in a large group of people with cancer over a longer period. In this study, the sample size of people with cancer and the large dataset enable methods to be applied to detect underlying processes that predict labor force participation. In addition, access to large data sets of the general population will help to extract well-defined groups matched by age, sex and other socioeconomic variables. Nevertheless, the observational nature of much epidemiological research has drawn criticism including "excess expense, repudiated findings, studies that offer small incremental knowledge, inability to innovate at reasonable cost and failure to identify research questions with the greatest merit".[32] This project therefore has a clear strategy to extend the collection of epidemiological research beyond discovery and causal research to include multilevel analysis of socioeconomic context and evaluation of health care interventions and implementation of social benefit programs. By enabling a high degree of transparency and interdisciplinary collaboration, the CANWORK study will exploit the advantages of Norway's registry structure to provide a strong scientific foundation, which hopefully will accelerate the translation of the scientific discoveries into health benefits for people with cancer.

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Ethics approval and informed consent: The study is conducted in accordance with the Declaration of Helsinki. The Central Norway Regional Committee for Medical and Health Research Ethics (Region 5) (project no. 2016/ 830/REK Midt) and the Norwegian Data Protection Authority (Project no: 0119) have approved the project related to the use of registries. The guidelines for storing, transmitting and deleting data from the Norwegian Data Protection Authority have been followed. All data are anonymous so that individuals cannot be identified directly or indirectly.
Informed consent from patients are not required according to regulations from The Central Norway Regional Committee for Medical and Health Research Ethics and The Norwegian Data Protection Authority.

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